



DEPARTMENT OF HEALTH & HUMAN SERVICES

COPY

m3759n

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

May 12, 2000

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-45

Sharon K. Zimmer, Vice President
The Sandwich Shoppe
134 Grimes Street
Eugene, Oregon 97402

Warning Letter

Dear Mrs. Zimmer:

We inspected your firm located at 134 Grimes Street, Eugene, Oregon, on February 16, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to Linda D. Roberts, Plant Supervisor, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for tuna salad sandwiches, to control the food safety hazards of pathogen growth.
2. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for any of the following eight areas of sanitation:
 - a. Safety of water;
 - b. Condition and cleanliness of food contact surfaces;

Sharon K. Zimmer, Vice President
The Sandwich Shoppe, Eugene, OR
Re: Warning Letter SEA 00-45
Page 2

- c. Prevention of cross-contamination;
- d. Maintenance of hand washing, hand sanitizing and toilet facilities;
- e. Protection of food, food packaging material, and food contact surfaces from adulteration;
- f. Proper labeling, storage, and use of toxic compounds;
- g. Control of employees with adverse health conditions; and
- h. Exclusion of pests.

This is a "serious" violation because the product is ready-to-eat and was brought to your attention in our letter to you dated September 17, 1999.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

For your information, our investigator also noted during the inspection that your HACCP plan did not list the critical control point of label review for controlling the food safety hazard of allergens (eggs and wheat) in your tuna salad sandwiches. Our Center for Food Safety and Applied Nutrition (CFSAN) and Office of Seafood are currently in the process of clarifying their position on this issue and a formal policy has not been issued.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Sharon K. Zimmer, Vice President
The Sandwich Shoppe, Eugene, OR
Re: Warning Letter SEA 00-45
Page 3

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483

21 CFR PART 123

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: with disclosure statement
OSDA